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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,072	05/10/2005	Andreas Van Eikeren	H01.2-11733-US01	8652
499 7590 06/09/2008 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344				
EXAMINER				
LEWIS, RALPH A				
ART UNIT		PAPER NUMBER		
3732				
MAIL DATE		DELIVERY MODE		
06/09/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/517,072

**Applicant(s)**

EIKEREN ET AL.

**Examiner**

Ralph A. Lewis

**Art Unit**

3732

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2, 3, 5-12 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 5-12 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **Objection to the Specification**

The reference to the claims at page 3, line 25 is not in accordance with U.S. practice. Moreover, claim 14 is no longer pending and if issued the claims would be renumbered.

### **Rejections based on Prior Art**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, 9-12 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Dragan (US 5,676,543).

Dragan discloses a method for isolating tooth material comprised of providing an addition reaction silicone (A-silicone)(column 3, line 25), a condensation silicone (C-silicone)(column 3, line 24) and/or polyethers (column 3, line 23) 10 that is mixed from a base portion and a catalyst portion and then "placed about the lower teeth 12, 12' and gum 14 and allowed to set" (emphasis added - column 3 lines 55-56). After the material 10 is set (cross-links in a self-cure manner) it forms an "impression 20 [that] closely conforms to the shape of the teeth 12, 12' and gum 14" (emphasis added - column 4, lines 1-3). The material 10 is removed from the patient's mouth and "filled

Art Unit: 3732

with a layer of flowable, syringeable or less viscous material 18" (column 4, lines 7-9) which maybe any of the silicone materials used for tray 10 (note column 4, lines 23-24). The flowable material 18 is placed "to flow around the teeth 12, 12' and gum 14" (emphasis added – column 4, line 30) where it is then allowed to set before removal. Material 18 and its use by Dragan, meet the "covering composition" limitations and it's broadly claimed method of use. The flowable material 18 is not applied to the isolated and exposed tooth material 12 at the right side of Figures 1, 2, 5 and 6 which is capable of being treated with a liquid dental treatment material. It is noted that the present claims specifically call only for a method of isolating tooth material to be treated and not a method of isolating and treating tooth material.

In regard to the limitation that the material is to adhere to the patient's gingival tissue, the examiner is of the position that the Dragan material adheres (at least partially) to a patient's gingival. If applicant's C-silicone is capable of adhering to the gingival, then so is the Dragan C-silicone; the laws of physics apply equally to applicant and the prior art. Applicant discloses, nor claims, any special ingredients in the prior art C-silicone (or A-silicone or polyethers) that make it capable of adhering to soft tissues that other such materials do not typically include.

In response to the present rejection applicant argues that Dragan "does not disclose to apply a composition to the gum around the tooth material to be treated and not onto the tooth material to be treated." The examiner disagrees; Dragan clearly illustrates teeth 12 to the right of Figures 1, 2, 5 and 6 that are left exposed and isolated from the teeth and gum tissue to which the Dragan composition has been applied. The

Art Unit: 3732

exposed and isolated teeth 12 to the right in Figures 1, 2, 5 and 6 are capable of being treated with a liquid dental treatment means (such as a whitening agent). Again applicant continues to construe the claims much more narrowly than the broad language of the claims require.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dragan (US 5,676,543).

Adjusting the ingredients so that the setting times fall within the ranges claimed would have been obvious to one of ordinary skill in the art as a matter of routine in practicing the Dragan invention.

Claims 2, 3, 5-12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et al (US 6,305,936) in view of Futami et al, (US 4,778,832) Hare (US 5,661,222), Kamohara et al (US 6,291,546), Zech et al (US 6,677,393), Amstutz et al (US 4,559,013) and Kostner et al (US 4,204,324).

Jensen et al teach the application of a flowable material 28 to the gums of a patient which quickly cross links and isolates the teeth 14 which are to be treated from

the gum tissue which is protected behind the applied composition. Jensen et al disclose that the barrier material 28 is a methacrylate composition mixed immediately prior to or during use and applied with a syringe 30 before it cures. While Jensen et al disclose methacrylates, rather than the claimed addition and condensation silicones, Jensen et al do make it clear that other materials having similar properties may be used to accomplish the method (note particularly column 7, lines 9-12).

A-silicones and C-silicones that are mixed in a liquid state prior and then cured by cross linking are well known and commonly used in the dental arts as impression materials for the teeth and gums as evidenced, for example by, Futami et al, Hare, Kamohara et al and Zech et al. It is further known in the art to use such easily shaped silicones to create a thin layer shield over selective teeth and gums as taught by Amstutz et al and Kostner et al. To have merely substituted common dental A-silicones and C-silicones which are known in the art to make beneficial shields which cover a patient's teeth and/or gums as taught by Amstutz et al and Kostner et al for the methacrylate compositions disclosed by Dragan would have been obvious to one of ordinary skill in the art, particularly in view of Dragan's disclosure that other compositions are capable of performing the disclosed method.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 3732

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(571) 272-4712**. Fax (571) 273-8300. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Cris Rodriguez, can be reached at (571) 272-4964.

R.Lewis  
June 5, 2008

/Ralph A. Lewis/  
Primary Examiner, Art Unit 3732